

WHAT IS CLAIMED IS:

1. A method for prophylaxis or treatment of benign prostatic hypertrophy (BPH) comprising administering an effective amount of lonidamine or a lonidamine analog to a human subject in need of such treatment.

2. The method of claim 1 comprising administering lonidamine to the subject.

3. The method of claim 1 wherein the subject is not being treated for cancer.

4. The method of claim 3 wherein the subject is not diagnosed with cancer.

5. The method of claim 1 wherein the subject has a serum PSA greater than about 2 ng/ml.

6. The method of claim 5 wherein the subject has a serum PSA less than about 10 ng/ml.

7. The method of claim 1 wherein the lonidamine or lonidamine analog is administered in combination with another treatment for BPH.

8. The method of claim 7 wherein the other treatment is:

- a) administration of an alpha-blocker;
- b) administration of a 5-alpha-reductase inhibitor;
- c) administration of zinc; or
- d) a surgical procedure.

9. The method of claim 2, wherein lonidamine is administered at least once per week for at least 4 weeks.

10. The method of claim 2, wherein lonidamine is administered at least once daily for at least five days.

11. The method of claim 9 wherein the daily dose is between about 1 mg and about 300 mg.

12. The method of claim 9 wherein the daily dose is between about 300 mg and about 5 grams.

13. The method of claim 9 wherein the daily dose is 150 mg p.o. TID.

14. The method of claim 1, wherein lonidamine is administered as a unit dose oral pharmaceutical composition that is a sustained-release formulation comprising from about 1 mg to about 2000 mg lonidamine.

15. The method of claim 1 wherein, when compared to a baseline prior to the initiation of treatment, the subject's

- a) AUASI or IPSS score is decreased by at least 3 points;
- b) prostate size has decreased by at least about 20%; and/or
- c) serum PSA levels have decreased by at least about 20%,

when determined on or after 60 days after the initiation of treatment.

16. A method for treating BPH comprising (a) diagnosing BPH in a patient, (b) administering lonidamine or a lonidamine analog to the patient and (c) determining whether one or more manifestations of BPH are reduced in said patient.

17. A method for treating BPH comprising (a) administering lonidamine or a lonidamine analog to a patient diagnosed with BPH and (b) determining whether one or more manifestations of BPH are reduced in said patient.

18. A unit dose oral pharmaceutical composition for treatment of BPH comprising between 1 mg and 70 mg lonidamine.

5 19. A unit dose oral pharmaceutical composition for treatment of BPH comprising 200 and 1000 mg lonidamine.

20. A unit dose oral pharmaceutical composition that is a sustained-release formulation comprising from about 1 mg to about 2000 mg lonidamine.

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